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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	Jan W. Wadsworth

Food and Drug Administration

[Docket No. 00D-0785]

**Draft Guidance for Industry; Guidance on Medical Device Patient Labeling;  
Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance on Medical Device Patient Labeling." This draft guidance is not final nor is it in effect at this time. This draft guidance describes how to make medical device patient labeling understandable to and usable by patients (or family members or other lay persons caring for patients). It is intended to assist manufacturers in their development and reviewers in their review and evaluation of medical device patient labeling. This draft guidance is designed to help assure safe and effective use of medical devices through medical device patient labeling that informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

**DATES:** Submit written comments on this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance on Medical Device Patient Labeling" to the Division of Small Manufacturers Assistance (DSMA) (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305),

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Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Paula G. Silberberg, Center for Devices and Radiological Health (HFZ-230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-1217.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

The draft guidance provides information on the content, format, and organization of information that patients need to use medical devices safely and effectively. It also gives principles for writing and presenting patient information in a manner most understandable and usable to patients and their lay caregivers. With an increase in patient use of complex medical devices previously used primarily by skilled and knowledgeable health-care professionals, effective medical device patient labeling has become increasingly important in helping to assure the safe and effective use of devices.

### **II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on medical device patient labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

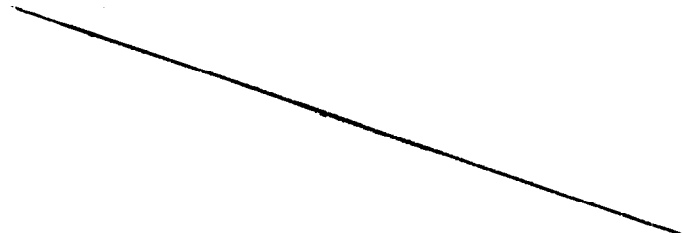
### III. Electronic Access

In order to receive “Guidance on Medical Device Patient Labeling” via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1128) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the Medical Device Patient Labeling, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The document entitled “Guidance on Medical Device Patient Labeling” will be available at <http://www.fda.gov/cdrh/HumanFactors.html>.

### IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in



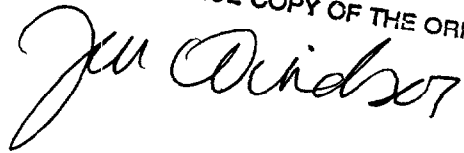
the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/28/00  
February 28, 2000



Linda S. Kahan  
Deputy Director for Regulations Policy  
Center for Devices and Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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